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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,634	01/24/2005	Yoram Sela	SELA5	3015

1444 7590 02/03/2009

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EXAMINER	
VU, JAKE MINH	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,634	SELA, YORAM	
	Examiner	Art Unit	
	JAKE M. VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,10,12-20,22,23 and 25-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9,10,12-20,22,23 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 11/17/2008.

- Claims 1, 9, 23, and 29 have been amended.
- Claims 1-7, 9, 10, 12-20, 22, 23, 25-30 are pending in the instant application.

Claim Rejections - 35 USC § 112

Claims 9, 22, and 23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **are withdrawn** in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

Claims 1, 3, 4, 16, and 19 rejected under 35 U.S.C. 102(b) as being anticipated by HEILIGENSTEIN (EP 0919236) **are maintained** for reasons of record in the previous office action filed on 05/15/2008 and as discussed below.

Applicant argues that the reference's formulation disclosed in the cited art clearly does not comprise venlafaxine hydrochloride, since the specific example in the reference used duloxetine. The Examiner finds this argument unpersuasive, because the reference disclosed venlafaxine can also be used (see pg. 3, line 8; pg. 14, line 48), wherein venlafaxine and duloxetine are classified in the same drug category of norepinephrine uptake inhibitor.

Applicant argues that the reference uses a different coating. The Examiner finds this argument unpersuasive, because as discussed in the previous office action, the

reference uses a hydrophilic polymer coating and cellulose derivative coating as claimed by Applicant.

Applicant argues that the cited publication does not provide any general disclosure of an enteric formulation that would be appropriate for a range of active compounds, including venlafaxine. The Examiner finds this argument unpersuasive, because one of ordinary skill in the art would simply replace venlafaxine in place of duloxetine.

Applicant argues that the two compounds are, chemically, entirely unrelated. The Examiner finds this argument unpersuasive, because the reference disclosed venlafaxine can also be used (see pg. 3, line 8; pg. 14, line 48), wherein venlafaxine and duloxetine are classified in the same drug category of norepinephrine uptake inhibitor.

Applicant argues that the prior art publication does not, and indeed could not, provide an implicit or generic disclosure that includes the instant venlafaxine formulation including a controlled release coating within its scope. The Examiner finds this argument unpersuasive, because as discussed above, the general disclosure with an example is the duloxetine example, wherein one of ordinary skill in the art would simply replace venlafaxine in place of duloxetine to arrive at Applicant's instant invention.

Claim Rejections - 35 USC § 103

Claims 1-7, 9-10, 12-20, 22-23, and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over HEILGENSTEIN (EP 0919236) **are maintained** for reasons of record in the previous office action filed on 05/15/2008 and as discussed below.

Applicant argues that Hiligenstein teaches and thus leads the skilled artisen to make an enteric formulation, whereas the objective of the present invention is to provide a controlled or extended release formulation. Thus, Hiligenstein does not and cannot teach the person of ordinary skill in the art what modifications are to be made in the Hiligenstein enteric formulation to provide an extended release formulation, because there is no reason given for doing so. The Examiner finds this argument unpersuasive, because an enteric formulation is a controlled release formulation. Additionally, as discussed in the previous office action, the prior art's composition is inherently capable of "controlled release of the venlafaxine hydrochloride over an extended time period" since the prior art's composition has the same ingredients as claimed by Applicant.

Applicant argues that venlafaxine hydrochloride, rather than duloxetine, is used as the active compound. The Examiner finds this argument unpersuasive, because the reference disclosed venlafaxine can also be used (see pg. 3, line 8; pg. 14, line 48), wherein venlafaxine and duloxetine are classified in the same drug category of norepinephrine uptake inhibitor.

Applicant argues that the claimed composition is an extended release formulation comprising an additional polymeric layer controllably releasing venlafaxine hydrochloride, in contrast, the cited publication teaches an enteric formulation which

provides for protection of an active compound during its passage through the stomach. The Examiner finds this argument unpersuasive, because as discussed above, the prior art's composition is inherently capable of "controlled release of the venlafaxine hydrochloride over an extended time period" or extended release, since the prior art's composition has the same ingredients as claimed by Applicant, such as an additional polymeric layer, wherein the polymeric layer is a cellulose derivative.

Applicant argues that the hydrophobic polymer used in the prior art example, HPMCAS, is not a functional equivalent of the hydrophobic polymers described and listed in the present invention. The Examiner finds this argument unpersuasive, because HPMCAS reads on a "hydrophobic polymer", such as "a cellulose derivative" (see Applicant's claim 13). Thus, HMPCAS is an equivalent of the hydrophobic polymers as claimed by Applicant.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/500,634	SELA, YORAM	
	Examiner	Art Unit	
	JAKE M. VU	1618	